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CONDITIONAL PETITION FOR EXTENSION OF TIME

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

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REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

New claims 13 and 14 are added, which are supported by Examples 1 and 2. Applicants do not believe the new claims introduce new matter. An early notice to that effect is earnestly solicited.

Claim 8 was rejected under 35 USC § 112, first paragraph, as claiming new matter. According to the Examiner, "[t]he term 'bacterial' is not disclosed or suggested by the specification as originally filed." In response, Applicants would direct the Examiner's attention to the very first paragraph of the specification, which reads as follows:

"The present invention relates to pharmaceutical preparations, their production as well as their use in human and veterinary medicine for the treatment and prevention of local *bacterial* infections."

[Emphasis added.] Clearly, the original specification contains *ipsis verbis* support for the term "bacterial," and claim 8 does not introduce new matter.

Claims 6, 7, 11 and 12 were rejected under 35 USC § 112, second paragraph, as being indefinite for failing to set forth method steps. In response, Applicants point out that claims 11 and 12 depend on claims 6 and 7, respectively, and claims 6 and 7 both expressly state that the pharmaceutical preparation is produced by "*forming* hardly water soluble antiphlogistic antibiotics salts." Applicants respectfully submit that the verb "forming" is sufficient under U.S. patent law to state a method step. Accordingly,

Applicants respectfully submit that claims 6, 7, 11 and 12 are in compliance with the second paragraph of § 112.

Claims 1, 2 and 6-8 were rejected under 35 USC § 102(b) as being anticipated by or in the alternative under 35 USC § 103(a) as being obvious over Bayens et al. ("Bayens"), *J. of Controlled Release*, 52: 215-2220 (1998), Renard et al. ("Renard"), *J. Fr. Ophthalmol.*, 19: 689-695 (1996) or Golub et al. ("Golub"), U.S. Patent No. 5,459,135. In response, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Regarding the issue of anticipation, Applicants point out what should be plain: This rejection is improper only if the cited references expressly or inherently teach what is now claimed. The Examiner does not point to any express teachings of the presently claimed salts. Accordingly, the Examiner must be relying on a theory of inherency, and, as such, the anticipation aspect of this rejection is proper only if what is presently claimed *necessarily* flows from the teachings of the cited prior art. *In re Robertson*, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Further, inherency is not established by probabilities or possibilities, and the mere fact that a property may result from a given circumstances is not sufficient; instead it must be shown that such property *necessarily* inheres in the thing described in the reference. *Id.*

The Examiner appears to take the position in the paragraph bridging pages 2-3 of the final rejection that the presently claimed salts would have been expected to form *in situ* in the references. However, as explained on pages 7-10 of the amendment dated October 14, 2005 (hereinafter "the previous amendment"), this is not necessarily the case. Taking Bayens, for example, if such salts had formed in Bayens *in situ*, such salts being the same as those instantly claimed, would have exhibited the same properties as those instantly claimed, namely, low solubility in water. Such salts, had they formed in Bayens, would have precipitated out of the solution, and, thus, there would have been some mention in Bayens of a precipitate. The fact that Bayens does not mention a precipitate strongly indicates that such salts of low water solubility were not formed, and,

therefore, there was, in fact, no inherent anticipation of the salts instantly claimed.

In the second paragraph on page 8 of the previous amendment, Applicants explained that the lack of salt formation in Bayens could readily be understood from the fact that Bayens used very low amounts of gentamicin sulphate and dexamethasone phosphate. Such amounts are too small to lead to observable salt formation. By way of explanation, Applicants directed the Examiner to compare the relatively large amounts of gentamicin sulphate and dexamethasone phosphate concentrations used in instant Examples 1 and 2 to bring about precipitation.

Respectfully, in answering this line of argument, the Examiner was required to point out some flaw in it. Rather than doing this, the Examiner simply responded that *in situ* formation was expected. Respectfully, this is not the case. Collectively, the facts suggest that salt formation is concentration dependent, and, due to the poor water solubility of the salts, salt formation is indicated by precipitation formation. Bayens uses low concentrations of the free bases, and no precipitate is mentioned, thus, indicating that salts did not form *in situ*.

Reviewing, on the issue of anticipation, there is no express teaching in Bayens of *in situ* salt formation, and Applicants have provided a cogent technical explanation why *in situ* salt formation was not inherent. Similar defects exist in Renard and Golub as explained on pages 8-10 of the previous amendment. Applicants respectfully request that the Examiner not repeat the anticipation aspect of this rejection. If the anticipation aspect is repeated, then Applicants respectfully request that the Examiner explain where in any of the cited references there is an express teaching of the instantly claimed salts. If there is no express teaching, then Applicants respectfully request that the Examiner explain in detail where in each reference an inherent teaching of the present salts can be found, and then also explain her position in detail (1) why it is that such salts must necessarily be formed and (2) where is the error in Applicants' position on pages 8-10 of the previous amendment why such salts were, in fact, not formed.

On the issue of obviousness, while inherency is a proper basis for anticipation, inherency is not a proper basis for obviousness. A person having ordinary skill in the art, having no knowledge that the respective components, when combined, would form low solubility salts suitable for use in treating bacterial infections, would not have found it obvious to combine such components to prepare such salts with a reasonable expectation of success. The cited prior art contains not the suggestion or the reasonable expectation of success to do what Applicants have done. Consequently, the cited references all fail to make out a prima facie case of obviousness.

In short, Applicants believe that the Examiner would be fully justified to reconsider and withdraw this rejection. An early notice that this rejection has been reconsidered and withdrawn is earnestly solicited.

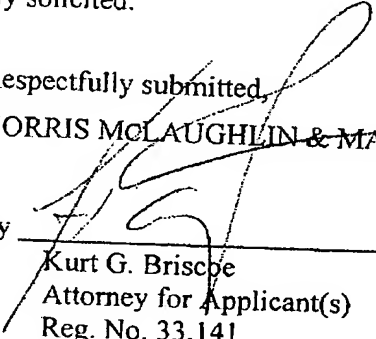
Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,
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By


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